NOV 19 2004

Planmed

K042671

510K) SUMMARY

DATE
November 16, 2004

PRODUCT, CLASSIFICATION NAME
Trade name: Planmed Sophie Nuance Classic
Common name: Mammographic x-ray system
Classification: 90 IZH, Class II
Regulation number: 892.1710

MANUFACTURER
Planmed Oy
Asentajankatu 6
FI-00880 Helsinki, Finland
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Contact person: Lars Moring

UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)
Planmed USA Inc.
100 North Gary Avenue, Suite A
Roselle, IL 60172
Phone: (630) 894 2200
Fax: (630) 894 4271
Contact person : Bob Pienkowski

INTENDED USE
The Planmed Sophie Nuance Classic is a mammography x-ray system, which is intended to be used to produce radiographs of the human breast. The device can be equipped with accessories to fulfil different diagnostic needs. Spot mammography is only used in combination with stereotactic needle biopsy guidance.

PRODUCT DESCRIPTION
The Planmed Sophie Nuance Classic is a conventional mammography x-ray system utilizing films and cassettes. This product is a modification of the previous devices Planmed Sophie and Planmed Sophie Classic, where the changes made are concentrated on the lower shelf construction (with easier assembly and better serviceability), a new Flex AEC system, more modern overall design and enhanced user friendliness. The modification also serves as a base to an easy upgradeability to full field digital imaging use in the future.

SUBSTANTIAL EQUIVALENCE
We consider this product to be similar in design, composition and function to the following devices introduced into commercial distribution after May 28, 1976:

K904953 Planmed Sophie

# K923471	Planmed Sophie with Cytoguide
# K951883	Planmed Sophie modification
# K962105	Planmed Sophie Classic
# K973493	Planmed Sophie Classic with Cytoguide
# K983659	Planmed Sophie modification
# K991826	Planmed Sophie with Maxview
# K013656	Planmed Sophie modification
# K021945	Planmed Sophie with Digiguide

The comparison of characteristics supports substantial equivalence. Planmed Sophie Nuance Classic is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2004

Planmed Oy
% Mr. Bob Pienkowski
Managing Director
Planmed USA, Inc.
100 North Gary Avenue, Suite A
ROSELLE IL 60172

Re: K042671
Trade/Device Name: Planmed Sophie
Nuance Classic
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammograhpic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: September 17, 2004
Received: September 29, 2004

Dear Mr. Pienkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042671

Device Name: Planmed Sophie Nuance Classic

Indications For Use:

The Planmed Sophie Nuance Classic is a mammography x-ray system, which is intended to be used to produce radiographs of the human breast. The device can be equipped with accessories to fulfil different diagnostic needs. Spot mammography is only used in combination with stereotactic needle biopsy guidance.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Logsdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042671